

REMARKS

Existing claims 1-68 are pending in the application and claims 1-23, 26, 44-50, and 61-68 are currently under examination on their merits. Claims 1, 5, 8, 12, 17, 22, 26, 44, 45, 61, and 63 through 68 are being amended, as shown above. These amendments are being made, in part, to further improve clarity, consistency, and readability of the claims, and also to either place the claims in condition for allowance, or, in the alternative, in better condition for appeal. These amendments are fully supported by the specification, add no new matter, and do not require any additional searches to be made by the Examiner.

It is noted that the previous response filed by the Applicants (on August 24, 2005, and responsive to the Office Action of March 24, 2005) fully applies to, and supports, the present amendments. Entry of these amendments, and reconsideration of the outstanding rejections in view of both the previously submitted response and the following additional arguments, is respectfully requested.

Claim Rejections under 35 USC § 112, 1st paragraph – Written Description

Claims 1-23, 26, 44-50 and 61-64 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicants traversed this rejection and provided arguments in their response mailed August 24, 2005. Applicants reaffirm these arguments and note that the recent decision of the United States Court of Appeals for the Federal Circuit in *Capon et al. v. Eshhar et al. v. Dudas* (Case No. 03-1480, -1481 (Interference No. 103,887), (Fed. Cir., August 12, 2005)(Fed. Cir. BBS)), supports these affirmations.

At issue in *Capon v. Eshhar v. Dudas*, was whether or not the specifications of Capon's United States Patent No. 6,407,221, and Eshhar's patent application Serial No. 08/084,994 provided sufficient "written description" of the disputed invention, under 35 U.S.C. § 112, first paragraph. The claims are directed chimeric genes having an antigen-binding domain-encoding DNA and a lymphocyte-receptor protein-encoding DNA combined into a unitary recombinant gene that directs the expression of a unitary chimeric protein.

Prior to the appeal to the Federal Circuit, the Board of Patent Appeals and Interferences (the Board), addressed the interference between Capon and Eshhar and held that the claims in the Eshhar application and the Capon Patent failed to meet the written description requirement. The Board stated: “both Eshhar and Capon claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.” *Capon v. Eshhar*, Interf. No. 103,887 (Bd.Pat.App.& Interf. Mar. 26, 2003) at 89.

In its decision to vacate and remand the appealed case back to the Board, the Federal Circuit concluded that the Board erred in refusing to consider the state of scientific knowledge with respect to the invention, and further, that the Board erred “in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.” In essence, the Federal Circuit indicated that there was sufficient written description of the invention because the chimeric genes disclosed in both specifications were prepared from known DNA sequences of known function. Furthermore, the Federal Circuit found that the use of functional language in the claims of Capon’s patent and Eshhar’s application was perfectly acceptable, even though these claims defined the invention by what it does (i.e., chimeric DNA that directs expression of a membrane-bound protein that initiates signaling in a host cell when its extracellular domain binds a specific ligand), rather than what it is (i.e., a defined sequence of nucleotides).

The situation considered by the Federal Circuit in *Capon v. Eshhar v. Dudas* is analogous to the instant case under examination, because the claimed subject matter of the instant case – isolated protein complexes comprising Tsg101 interacting with HIV GAGp6, or fragments or homologues thereof – are prepared from known proteins of known function, and further, the claims under examination include functional limitations that require the interacting polypeptides to actually interact and form a complex (i.e., wherein the first polypeptide is a fragment or homologue of Tsg101 that comprises a

UEV domain **and interacts with HIV GAGp6**). In view of this, and in further view of the fact that the specification provides extensive teachings on how to prepare isolated protein complexes and how to tell whether polypeptides interact to form such protein complexes, Applicants respectfully reassert that the claims under examination are fully supported and described by the specification, and that the specification contains sufficient written description to convince one of skill in the art that the inventors had indeed invented, and were in possession of, the isolated protein complexes of the claims.

As a separate but related matter, the Federal Circuit in *Capon v. Eshhar v. Dudas* also observed that:

The descriptive text needed to meet [the “written description” requirement] varies with the nature and scope of the invention at issue, and with the scientific knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science.

Capon v. Eshhar v. Dudas, Case No. 03-1480, -1481, (Fed. Cir., August 12, 2005)(Fed. Cir. BBS), at page 13.

As noted previously, the instant invention under examination comprises protein complexes formed by the interaction of two well-characterized proteins – Human Tsg101 and HIV GAGp6 – and the instant application teaches “the UEV domain of the Tsg101 protein and the PTAP motif of the HIV GAGp6 are responsible for the interactions” (Specification, page 38, second paragraph). Consequently, the pending claims were written to include protein complexes formed through the interaction of fragments and homologues of Tsg101 that comprise a UEV domain interacting with fragments and homologues HIV GAG and HIV GAGp6 that comprise a late domain, or PT/SAP late domain motif. Language reading upon protein complexes comprising fragments and homologues of Tsg101 and HIV GAGp6 was purposefully included in the claims in order to provide adequate protection for that which the Applicants regarded as their invention. Additionally, the claims were written to cover protein complexes comprising fragments and homologues of Tsg101 and HIV GAGp6 because, at the time the invention was made, it was well known in the art that if two proteins were found to interact, specific fragments and homologues of these proteins would reasonably retain the ability to interact, so long as they also contained the interaction domains (or functional homologues

thereof) responsible for the interactions between the full-length proteins. Such was the state of relevant knowledge at the time the invention was made and at the time the instant application was filed.

In view of this, Applicants respectfully assert that, in contrast to the the Federal Circuit's directive in *Capon v. Eshhar v. Dudas*, the law is not being applied to the instant invention **in view of the state of relevant scientific knowledge**. In other words, the Office's rejection of the pending claims under 35 U.S.C. § 112, first paragraph, for alleged lack of written description essentially ignores the scientific knowledge of Tsg101 and its UEV domain, HIV GAGp6 and its late domain, and the nature of protein-protein interactions that was already in existence at the time the instant invention was made. Consequently, Applicants respectfully assert that, in formulating its written description rejection, the Office has not adequately taken into account the state of knowledge in the field at the time the invention was made.

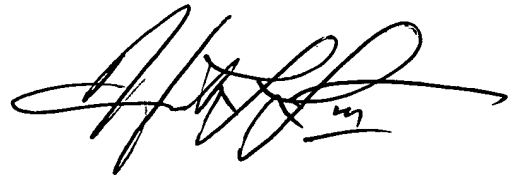
Accordingly, Applicants respectfully request that written description rejection be withdrawn.

CONCLUSION

Applicants believe that once the amendments proposed above have been incorporated into the pending claims, and the arguments presented above, and in their response dated August 24, 2005, are considered, the outstanding rejections will be withdrawn and the pending claims will be in condition for allowance. Consequently, Applicants respectfully request that a timely Notice of Allowance be issued in this case. In order to expedite allowance of this application, the Examiner is invited to telephone the undersigned via his direct office line at 801-883-3463.

It is believed that no extension of time or fee is required with this supplemental response. If this is incorrect, an extension of time as deemed necessary is hereby requested, and the Commissioner is hereby authorized to charge any appropriate fees or deficiency or credit any over payment to Deposit Account no. 50-1627.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'H. Ley III', with a stylized flourish at the end.

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September 8, 2005

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